

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

PAR PHARMACEUTICAL, INC., PAR
STERILE PRODUCTS, LLC, and ENDO
PAR INNOVATION COMPANY, LLC,

Plaintiffs,

v.

EAGLE PHARMACEUTICALS INC.,

Defendant.

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C.A. No. 18-823-CFC



DECLARATION OF BRIAN M. GOLDBERG

I, Brian M. Goldberg, declare pursuant to 28 U.S.C. §1746 as follows:

1. I am an attorney at the law firm Dechert LLP, representing Plaintiffs Par Pharmaceutical, Inc., Par Sterile Products, LLC and Endo Par Innovation Company, LLC (collectively, “Par”) in the above-captioned litigation.
2. I submit this declaration upon my personal knowledge in support of Par’s Concise Counter Statement of Facts in Opposition to Eagle’s Concise Statement of Undisputed Facts.
3. Attached hereto as Exhibit A is a true and correct copy of Module 3.2.P.8.2 Post Approval Stability Protocol and Stability Commitment from Sequence 19 of ANDA No. 211538, produced at EAGLE0047249.
4. Attached hereto as Exhibit B is a true and correct copy of Field Alert Report Submission, Questions and Answers, FDA Draft Guidance for Industry, dated July 2018.
5. Attached hereto as Exhibit C is a true and correct copy of Module 3.2.P.8.1 Stability Summary and Conclusion from Sequence 19 of ANDA No. 211538, produced at EAGLEVAS0047328.

6. Attached hereto as Exhibit D is a true and correct copy of excerpts from Module 3.2.P.2 Pharmaceutical Development from ANDA No. 211538, produced at EAGLVAS0000670.

7. Attached hereto as Exhibit E is a true and correct copy of an [REDACTED]
[REDACTED] produced at AMRIVAS0114545.

8. Attached hereto as Exhibit F is a true and correct copy of SVA001/002/003 Data Record produced at AMRIVAS0114554.

9. Attached hereto as Exhibit G is a true and correct copy of a 2017 Registration Batch, SVA001 Long Term Stability data from Sequence 19 of ANDA No. 211538, produced at EAGLEVAS0047274.

10. Attached hereto as Exhibit H is a true and correct copy of excerpts of the Opening Expert Report of Lee E. Kirsch, Ph.D. Regarding Infringement, dated November 15, 2019.

11. Attached hereto as Exhibit I is a true and correct copy of excerpts of the Reply Expert Report of Lee E. Kirsch, Ph.D. Regarding Infringement, dated January 20, 2020.

12. Attached hereto as Exhibit J is a true and correct copy of the Supplemental Expert Report of Lee E. Kirsch, Ph.D. Regarding Infringement, dated May 8, 2020.

13. Attached hereto as Exhibit K is a true and correct copy of a document titled Vasopressin Injection USP Stability Analysis, A Statistical Evaluation of pH from Sequence 19 of ANDA No. 211538, produced at EAGLEVAS0047242.

14. Attached hereto as Exhibit L is a true and correct copy of Module 3.2.P.5.1 Specifications from Sequence 19 of ANDA No. 211538, produced at EAGLEVAS0046173.

15. Attached hereto as Exhibit M is a true and correct copy of excerpts of the transcript of the deposition of James Romito, dated October 9, 2019.

16. Attached hereto as Exhibit N is a true and correct copy of SVA008 Executed Batch Record, produced at EAGLEVAS0048569.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on: May 8, 2020

/s/ Brian M. Goldberg
Brian M. Goldberg